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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,354	11/07/2001	Julio C. Spinelli	279.373US1	4381

21186 7590 07/19/2007

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	**PAPER NUMBER**
3762	
MAIL DATE	**DELIVERY MODE**
07/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/008,354	SPINELLI ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6, 7, 10-18, 20, 21, 24-26, 30-41, 43, 46* is/are rejected.

7)☒ Claim(s) *5,8,9,19,22,23,27-29,42,44 and 45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, 7, 10, 12-18, 20, 21, 24-26, 30, 32-35, 37-41, 43, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Bardy (7070562). Bardy teaches the use of an IMD storing data characteristic of a patient (column 5), transmitting the information to a programmer, 14, and then over a wide area network (the internet, column 6), to a remote server. The remote server analyzes the data and provides feedback (the claimed "prescribing") to the programmer to reprogram instructions in the IMD (e.g. column 9, claim 1, etc). The remote server contains several "expert prescription systems", such as peer-to-peer and sibling-to-sibling (column 10), since these different comparisons are set up, defined, and implemented by experts/physician/technicians to determine when to reprogram the device. In addition, these same prescription systems are considered the "custom prescription system" since they are customized to the particular patient and/or IMD. Regarding claims 12, 13, and 14, the IMD is considered to be a patient monitoring system and a patient records computer system since the IMD both monitors and records patient information and interfaces with the programmer.

Claims 1-3, 6, 10-17, 20, 24-26, 30-41, 43, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Haller et al (2002/0013613). Haller teaches the use of an IMD storing data

characteristic of a patient (e.g. paragraph 88), transmitting the information to a programmer, 100/110, and then over a wide area network to a remote expert data center (paragraph 81). It is noted that device 100/110 is a programmer since it receives information from the IMD and programs the IMD with new parameters (e.g. paragraphs 89, 105, etc). The remote server analyzes the data and provides feedback (the claimed "prescribing", paragraph 169) to the programmer to reprogram instructions in the IMD. The device/programmer 100 has a user interface 108 that accepts characteristics of the patient to reprogram the device (e.g. paragraphs 96, 163). Regarding claims 12, 13, and 14, the IMD is considered to be a patient monitoring system and a patient records computer system since it both monitors and records patient information and interfaces with the programmer. The remote server contains an expert system since it is called an expert system or contains a custom prescription system since the device is customized to the particular patient and/or IMD.

Claims 1-3, 6, 10, 12-17, 20, 24-26, 30, 32-35, 37-41, 43, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Snell (6249705). Snell teaches the use of an IMD transmitting patient data to the programmer (column 8, lines 26-35) and the server analyzing the data and prescribing new parameters for the IMD (column 9, lines 30-45). Regarding claims 12, 13, and 14, the IMD is considered to be a patient monitoring system and a patient records computer system since it both monitors and records patient information and interfaces with the programmer. The remote server contains an expert system or custom prescription system since it is provided by experts/physicians/technicians to accurately program the device and since the device is customized to the particular patient and/or IMD.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 7, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haller et al or Snell. Haller or Snell discloses the claimed invention except for the multiple expert and/or custom prescription systems. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the prescription method and system as taught by Haller or Snell, with the use of multiple expert and/or custom prescription systems since it was known in the art that prescription systems use multiple expert and/or custom prescription systems to allow different rules to be applied to different patient parameters in order to program different functions, such as pacing rate, defibrillation therapy, sensor rate, etc, in the IMD to meet the hemodynamic and therapeutic needs of the patient.

Allowable Subject Matter

Claims 5, 8, 9, 19, 22, 23, 27-29, 42, 44, and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 2/27/07 have been fully considered but they are not persuasive. The argument that the "Applicant has used an electronic search engine to search the entire Bardy disclosure and is unable to find reference to a prescription" (and similar argument for Snell) is not persuasive. As the attorney is well aware, a reference used in a rejection does not have to have a specific word for word match to the claim(s), but the reference must meet the limitations of the claim(s). Since the word "prescription" has not been specifically defined in the specification, the examiner has given the word its broadest reasonable interpretation as meaning "to lay down a rule; dictate" or "to lay down as a guide, direction, or rule of action", "recommend a remedy", "to specify with authority", or "to designate or order the use of as a remedy". Since Bardy and Snell meet the limitation(s) of prescribing by providing rules/remedies for the implantable device in order for the device to function properly, it has met the claim limitation of "prescribing a programmable parameter of a medical device" and therefore has a prescription system.

The argument that Haller does not disclose a programmer in communication with a computer network (central server) is not persuasive. Haller discloses a programmer as device 100/110 since that device programs new parameters into the IMD and is therefore a "medical

device programmer" and meets that specific claim limitation. Although Haller's device 100/110 might not be the same as the applicant's programmer, Haller's device nonetheless meets the claimed limitation of a medical device programmer. In addition, Haller's device 100/110 is in communication with a computer network (central server) as discussed in paragraphs 81, 82, 85, etc. and seen in figures 6, 8, etc. The argument that the 103 rejections do not provide a teaching, motivation or suggestion to combine is not persuasive since the rejections provide the motivation, such as "to allow different rules to be applied to different patient parameters in order to program different functions, such as pacing rate, defibrillation therapy, sensor rate, etc, in the IMD to meet the hemodynamic and therapeutic needs of the patient".

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762

7/6/7

GRE
July 9, 2007